

Dockets Management Branch Date 2/14/99
The Food and Drug Administration
Department of Health and Human Services, Rm. 1-23
12420 Parklawn Dr.
Rockville, MD 20857

NOV 17 P1:25

Re: 99P-1340/CP 1 Petition to Have *Eternity eau de parfum* "Misbranded"

Dear Sir or Madam:

In May, 1999, the Environmental Health Network (EHN) submitted the above petition to have Calvin Klein's "**Eternity eau de parfum**" declared misbranded. I am writing because I fully support this petition and request that the FDA give it careful attention with regard to your regulations 21 CFR Sec. 740.1, 21 CFR Sec. 740.2, and 21 CFR Sec. 740.10. Regulation 21 CFR **Sec. 740.10** specifically states:

"Each ingredient used in a cosmetic product and each finished cosmetic product shall be **adequately** substantiated for safety prior to marketing. Any such ingredient or product whose safety is not adequately substantiated prior to marketing is misbranded unless it contains the following conspicuous statement on the principal display panel:

"Warning--The safety of this product has not been determined."

As the petitions shows, "Eternity" contains toxic ingredients and ingredients whose safety have not been substantiated. There is no warning label on its packaging.

We all have a right to know the status of safety testing of the ingredients in products such as "Eternity" so that we can protect ourselves and our families **from** toxic chemicals that may cause health problems. Most people are not aware that most fragrance materials have only limited safety testing. They wrongfully assume these products are safe to use in any **setting and are surprised** when people complain.

Like tobacco smoke, the harmful chemicals currently used in these products may affect the health of many people, including people with asthma, chemical sensitivities, chronic fatigue, and other environmental illnesses. Children are particularly vulnerable to toxic chemicals found in products purchased and used by their parents, care givers and teachers.

When I am exposed to fragrance products, such as "Eternity," I experience (list here):

headaches - others I know experience worse!
foul taste in mouth

Please act on behalf of the millions of people who have suffered physical illness and injury resulting **from fragrance** exposure at work, at school and in social settings. These toxic chemicals act as powerful barriers to people disabled by asthma and chemical sensitivities. Because of this, toxic chemicals in fragrances have already ruined countless lives. Thank you.

Sincerely,

Name Sheila A. Gallagher

Address; city/state/zip sq College Ave. Gorham, ME 04038

99P-1340

C 525

Last Chance for Fragrance Petition!

November 11th may be the last day to support the petition to the FDA to have **Calvin Klein's** Eternity eau de **parfum** labeled as misbranded. Analysis of Eternity proved it contained ingredients that were toxic and/or whose safety had not been adequately documented. Any product whose safety is not substantiated prior to marketing is misbranded unless it contains a label warning that its safety has not been determined. Eternity is not so labeled.

The Environmental Health Network (CA) filed the petition May 11, 1999 with the FDA, who has 180 days to respond. Comments may be filed until the FDA responds, so there is not a specific deadline, but the **FDA could** respond sooner. **Mailed** letters are preferred, but fax or **email** is accepted.

Anonymous comments are not accepted.

Eternity is only one of many fragrances that may trigger severe reactions in people with asthma, MCS, migraines, GWS, and multiple other illnesses, but is representative of the disregard for health and safety by the fragrance industry that rarely discloses the contents of its products nor the potential side effects.

**Massachusetts Association for the
Chemically Injured, Inc.**
P.O. Box 754
Andover, MA 01810

exp. date 11/99

Shiela Gallagher
59 College Ave.
Gorham, ME 04038

The sample letter to FDA on the **back** of this page may be copied if you wish.

DOCKET NUMBER: **99P-1340/CP 1** (use this on all correspondence.)

Mail letters to:

Dockets Management Branch
The Food and **Drug Administration**
Department of **Health** and Human Services, Rm. 1-23
12420 **Parklawn** Drive; Rockville, MD 20857

Letters also may be faxed or **emailed**.

Fax: **301-827-6870**

Email: fdadockets@oc.fda.gov

This is our last and best chance to let policy **makers, media and healthcare** providers know **about the health hazards** in fragrance products and **how they affect our lives**.

Information is **online** at The Fragrance Information Network site:

<http://www.ameliaww.com/fpin/petition%20index.htm>

and at the Environmental Health Network site:

<http://users.lanminds.com/~wilworks/ehindex.htm>



04038+1562

